

## **Remarks**

### **Claim Status**

Claims 16, 18, 20-27, 29, 30, 35, and 37-50 are pending and at issue in the present application.

### **Explanation of Claim Amendments**

Claims 16, 18, 37, 41, and 49 have been amended to place the claims in better form for consideration on appeal by addressing certain formal rejections newly presented in the pending Office action. See M.P.E.P. § 714.13; 37 C.F.R. § 1.116(b)(2). Support for the amendments to claims 16, 18, 37, 41, and 49 can be found in at least paragraph [0023] and the claims as originally filed. Therefore, entry of the amendments presented is requested.

### **Interview Summary**

The undersigned thanks Examiners Raj and Sereboff for courtesies extended during a telephonic interview conducted on December 22, 2010. Claim 16 was discussed in light of the applied references, and the proposed amendments to the claims presented herein were explained by the undersigned. No substantive agreement was reached as to allowability of the claims.

### **The 35 U.S.C. § 101 Rejections**

Claims 35, 37-50 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. These rejections are traversed.

It is stated in paragraph 7 of the Office action that the 35 U.S.C. § 101 rejection as to claim 35 has been “withdrawn in light of the applicant’s amendment”, yet in the next paragraph, paragraph 8 of the Office action, it is stated that claim 35, along with claims 37-50, are rejected under 35 U.S.C. § 101. In view of the fact that there were no prior pending § 101 rejections (see Office action dated April 29, 2010), it is unclear as to the actual status of these rejections.

Regardless of the aforementioned inconsistency, Applicant respectfully traverses the 35 U.S.C. § 101 rejections as to claims 35 and 37-50 as being based on a clear error of law. Under 35 U.S.C. § 101, “Whoever invents a new and useful process . . . may obtain a patent therefore, subject to the conditions and requirements of this title.” In *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), the Supreme Court clarified that there are only three specific judicially created exceptions to the plain meaning of this statutory right: laws of nature, physical phenomena, and abstract ideas. *Id.*, at 3225. Further, although the machine-or-transformation test is a useful clue as to patent eligibility of

process claims under § 101, it is not the sole test for deciding whether an invention is patent eligible. *Id.*, at 3227. However, a “claimed process is surely patent-eligible under 35 U.S.C. § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” *In re Bilski*, 545 F.3d 943, 952 (Fed. Cir. 2008) (en banc), *aff’d sub nom. Bilski v. Kappos*, 130 S. Ct. 3218 (2010).

With regard to claims 35 and 37-50, there is no suggestion on the record that the claimed invention is merely a law of nature, physical phenomena, or an abstract idea. Further, independent claims 35 and 37 each recite a method “performed by a computer navigation system”, wherein the computer navigation system performs various steps recited by the claims. In addition, each of independent claims 35 and 37 recites the step of displaying a representation related to a consequent step on a display screen. Consequently, the methods of claims 35 and 37-50 are not reciting merely an abstract idea, and in fact are tied to at least one particular machine and transform at least some matter. Therefore, the rejections under 35 U.S.C. § 101 are clear legal error and should be withdrawn.

### **The 35 U.S.C. § 112 Rejections**

Claim 16 is also rejected under 35 U.S.C. § 112 for lack of antecedent basis as to the claim’s recitation of the limitation “the consequent step”. Applicant respectfully traverses this rejection. In light of the amendment to claim 16, this rejection should now be withdrawn.

Independent claims 16 and 37 and all claims dependent thereon also stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention. Specifically, it is alleged in the Office action that “[i]t is unclear to the Office what ‘*identifying the consequent step*’ mean[s], and further what step is being identified or what step is the consequent step” (emphasis in original). This rejection should be withdrawn in view of the amendments presented herein, which replace the term “identifying” with the previously used and accepted term “determining,” and also the discussion presented immediately hereinafter regarding the term “consequent step” in claim 16.

In answer to the clarification requested in the Office action, one commonly understood meaning of “consequent” applicable in the present context is: “following [especially] as a result”. Webster’s Third New International Dictionary, 483 (2002). The “consequent step” is the step that follows as a result of a determination made by the computer navigation system as to which step in

the multi-step operation should be displayed on the navigation screen at any given time as a consequence of the then present conditions. In the present invention, the consequent step to be performed after the current step can be a step other than the current step or the next step, such as the previous step or a step after the next step, depending on, among other things, what tool is identified by the computer navigation system and what the identity of the current step is. Thus the step of determining a consequent step involves determining what step out of several possible choices should be performed next as a consequence of the present conditions recited.

In view of the amendments and explanations herein, these rejections should now be withdrawn.

### **Rejections Over the Prior Art**

Claims 16, 18, 20-27, 29, 30, 35, and 37-50 stand rejected as obvious over Malackowski et al. (U.S. Publication No. 2003/0093103) in view of Van Der Brug (U.S. Patent No. 5954648) and DiGioia, III et al. (U.S. Patent No. 6205411). These rejections are traversed.

None of the applied references discloses or suggests a computer navigation system for implementing a multi-step surgical procedure that comprises a first sequence of steps, as recited in amended claim 16, wherein the computer navigation system comprises means for identifying a current step within the multi-step surgical procedure and means for analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence.

Further, none of the applied references discloses or suggests a method performed by a computer navigation system of determining and displaying a consequent step of a procedure comprising a first sequence of steps, as recited in claim 35, including identifying a current step of the procedure, analyzing whether the component is acceptable for use in steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence, and determining the consequent step based on the location, the identity of the component, and the identity of the current step.

Further still, none of the applied references discloses or suggests a method performed by a computer navigation system of determining and displaying a consequent step of a surgical procedure comprising a first sequence of steps, as recited in amended claim 37, including identifying a current step of the surgical procedure and analyzing steps of the surgical procedure including a step other

than the current step or an immediately subsequent step in the first sequence.

**A. The Applied References Do Not Disclose Means For or The Step Of Determining A Current Step.**

It is conceded in the Office action that the limitation “identifying a current step” contained in claims 16, 35, and 37 is not disclosed in Malackowski or Van Der Brug. Rather, it is alleged in the Office action that the deficiencies in those references are supplied by DiGioia. Contrary to the arguments in the Office action, however, DiGioia also does not disclose this limitation, and therefore the Examiner’s rejections are traversed.

In regards to claim 16, it is alleged on page 6 of the Office action that “Malackowski/Van Der Brug do not disclose the following limitation, however DiGioia, as shown, does: *means for identifying a current step within the multi-step procedure*; (see at least DiGioia [0131])” (emphasis in original). On pages 12-14 of the Office action, the same rejection is provided for claims 35 and 37, which have different claim language. Claim 35 recites the step of “identifying a current step of the procedure”; and, claim 37 recites the step of “identifying a current step of the surgical procedure”.

The applicants agree that, as conceded in the Office action, neither Malackowski nor Van Der Brug disclose the aforementioned limitation. See pages 6 and 12-14 of the Office action.

However, DiGioia does not contain a paragraph [0131] as it is a published patent not a publication. Thus, it is unclear where support for these rejections is being found. Furthermore, even if the entire DiGioia reference is considered, it does not supply the deficiencies of the Malackowski and Van Der Brug references. DiGioia merely discloses performing steps; it does not disclose or suggest either actually identifying a current step or any need for identifying a current step.

Therefore, the applied references do not disclose all of the recited claim elements, and the applied references do not support a *prima facie* case of obviousness.

**B. Malackowski Does Not Disclose Analyzing A Step Other Than The Current Step Or An Immediately Subsequent Step.**

It is also averred in the Office action that Malackowski discloses the limitation of a means for analyzing or the step of analyzing “a step other than the current step or an immediately subsequent step” as recited variously in claims 16, 35, and 37. However, Malackowski does not disclose such limitation as discussed below. In addition, the Examiner does not cite to either Van Der Brug or DiGioia to support his rejections, and neither reference discloses or suggests the aforementioned limitation. Accordingly, these rejections are also traversed for these additional reasons.

In regards to claim 16, on page 4 of the Office action, the Examiner alleges that Malackowski discloses: *“means for analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence* [see at least Malackowski Claim:19 Fig:21 Items:350 & related text)” (emphasis in original). As to claim 35, the Examiner alleges on page 11 of the Office action that Malackowski discloses: *“analyzing whether the component is acceptable for use in steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence; (see at least Malackowski [0154-0158] Claim:19 Fig:21 Items:350 & related text)”* (emphasis in original). Furthermore, as to claim 37, the Examiner alleges on page 13 of the Office action that Malackowski discloses: *“analyzing steps of the surgical procedure including a step other than the current step or an immediately subsequent step in the first sequence; (see at least Malackowski Claim:19 Fig:21 Items:350 & related text)”* (emphasis in original). Finally, *“a step other than the current step or an immediately subsequent step”* (emphasis added) is analyzed by the present invention in relation to the current step, see at least paragraphs [0018] and [0021] of the application.

Malackowski discloses a surgical navigation system that implements a multi-step surgical procedure and reacts to identifying information from a surgical tool by displaying a warning and/or preventing actuation of the next step if the tool has unsatisfactory parameters for the next step in a predetermined sequence of surgical steps. These rejections of claims 16, 35, and 37 are supported, in part, on the language contained in claim 19 of Malackowski. Claim 19, however, merely disclose that a series of steps are performed in a specific sequence, and that after a certain determination is made in the current step, the next step is performed. That portion of Malackowski therefore at most suggests that the surgical navigation system advances to the next step in a multi-step surgical procedure based on the results of the current step. Malackowski, however, does not disclose that the surgical navigation system reacts by selecting a consequent step from a group of steps that include a step other than the current step or an immediately subsequent step in the sequence of the multi-step procedure.

The reasoning in the Office action also relies on Fig. 21 and “Items:350 & related text” to support the rejections of claims 16, 35, and 37. Those sections, however, merely illustrate how the surgical navigation system in Malackowski receives and uses data from various components to assist

the surgeon during the surgical procedure. Further, the reasoning relies on paragraphs [0154-0158] of Malackowski to support the rejection of at least claim 35. However, paragraphs [0154-0158] simply describe a procedure wherein, at each step of the surgical procedure, the surgical navigation system determines only if it is appropriate to advance to the next step of the procedure. The aforementioned portions of Malackowski do not disclose or suggest that the navigation system analyzes whether a tool or component for use in the surgical procedure is acceptable for use in any steps other than the current step or the next step of the procedure. Therefore, those sections of Malackowski do not supply the deficiencies identified herein, and the allegations to the contrary in the pending Office action are traversed.

Furthermore, Van Der Brug and DiGioia do not supply this deficiency pointed out in Malackowski. Van Der Brug discloses a surgical navigation system that tracks the location of a surgical instrument within a surgical field. However, Van Der Brug does not disclose that the surgical navigation system selects any steps of a multi-step procedure based on an identity of the surgical tool. DiGioia discloses a computer-assisted surgery planner and intra-operative guidance system including a navigation system that works progressively through a pre-defined sequence of pre-operative planning steps and intra-operative surgery steps. DiGioia does not disclose or suggest that the navigation system would ascertain an identity of a surgical tool and select a consequent surgical step that is a step other than the current step or an immediately subsequent step in the sequence of the multi-step procedure based on the identity of the surgical tool.

**C. Malackowski Does Not Disclose A Step Of Determining The Consequent Step Based On The Location, The Identity Of The Component, And The Identity Of The Current Step.**

It is alleged on page 11 of the Office action that Malackowski discloses the step of *“determining the consequent step based on the location, the identity of the component, and the identity of the current step; (see at least Malackowski [0087]”, as recited in claim 35.* This allegation is traversed.

In fact, paragraph [0087] of Malackowski discusses how a surgical navigation system uses data contained in a chip in a cutting accessory to configure the system so that it operates in a particular manner given the specific characteristics of the cutting accessory. The system is configured so that, for example, a hand piece motor will run at a preferred speed and in a preferred

mode for the cutting accessory when the system identifies the cutting accessory. Malackowski, therefore, at most discloses that attributes used in the next step of the pre-determined sequence are based on the location and identity of the component. Malackowski does not mention in paragraph [0087] or elsewhere that a step of determining the consequent step, which can be a step other than the current or immediately subsequent step, is based on the location and identity of the component.

Further, because Malackowski does not disclose the limitation of “identifying a current step” as conceded in the Office action, it is not possible for Malackowski to disclose that the next step is based on the location, identity of the component, and the identity of the current step. Thus, Malackowski does not disclose the deficiency identified herein, and the allegation to the contrary in the pending Office action is traversed.

#### **The Claimed Invention Provides Significant Benefits Over the Applied References**

In fact, the invention(s) as claimed variously in the pending claims overcomes deficiencies in the applied references by allowing the surgical navigation system to follow the selections of tools and/or components made by the surgeon during the procedure without requiring direct intervention with the software by a user, such as on a keyboard or other input device, to re-direct the software to a consequent step, even if the consequent step is a step other than the current step or the next step in the procedure. As explained in the specification, this frees the surgeon to jump to other steps in the procedure by merely introducing a new component into the tracking field of view of the navigation system, and eliminates the need to manually re-set the surgical procedure if the component is to be used in a step other than the current step or the immediately next step. The prior art would require the surgeon or some other operator to manually re-direct the surgical procedure to the desired step of the procedure if the component introduced into the tracking field is not acceptable for use in the current step or the immediate next step of the pre-defined sequence of surgical steps. Such manual intervention required by the prior art can be cumbersome and undesirable in the operating room environment. Therefore, the present invention is a substantial improvement over the prior art of the applied references by eliminating or reducing the need for such direct intervention with the navigation system.

#### **Conclusion**

Because the applied references do not disclose or suggest every element of claims 16, 35, and 37, and all claims dependent thereon, the applied references do anticipate or render obvious the


claims at issue, and the pending rejections should be withdrawn.

All of the pending rejections having been fully addressed and overcome herein, immediate allowance of the claims at issue and issuance of a Notice of Allowance is requested.

Respectfully submitted,

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